



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#19/2F
1/11/3

In re Application of MURPHY ET AL.)
) Art Unit: 1761
)
Serial Number: 09/728,443) Examiner: Wong, L.
)
Filed: December 1, 2000) Atty Docket: 5485

For: CALCIUM FORTIFIED DAIRY PRODUCTS AND METHODS OF
PREPARATION

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APPLICANT'S APPEAL BRIEF

Assistant Commissioner of Patents
Washington, D.C. 20231

Dear Sir:

The applicants of the above-identified U.S. patent application submits this Appeal Brief in support of an appeal from the final rejection of claims 1-22 and 25-72 in this application. The fee required under 37 C.F.R. §1.117(f) accompanies this brief.

REAL PARTY IN INTEREST

The above-identified patent application has been assigned to General Mills, Inc. which assignment has been duly executed by each of the inventors. The assignment has not yet been submitted to the U.S. Patent Office.

RELATED APPEALS AND INTERFERENCES

There does not exist any known related appeals or interferences which would directly affect, be directly affected by, or have a bearing on the decision in this case.

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STATUS OF CLAIMS

Claims 1-22 and 25-72 stand finally rejected and are herewith appealed. Claims 29 and 55 were amended on May 22, 2002. The remaining claims stand as originally filed. The application contains independent claims 1, 30, 40 and 52.

STATUS OF AMENDMENTS

No amendments to the claims have been made to the application after the final rejection dated July 31, 2002.

SUMMARY OF THE INVENTION

The present invention is concerned with nutritionally improved, cultured dairy products, such as milk beverages and yogurt products. Most importantly, a dairy product in accordance with the present invention includes a fine powdered calcium phosphate salt which has a reduced particle size defining a mean diameter $\leq 6\mu\text{m}$ so as to be visually undetectable in the final product, yet exhibiting acceptable organoleptic attributes in terms of grittiness and chalkiness, and also providing a total calcium content of 0.25% to 0.75%. In accordance with a method aspect for producing the calcium fortified products of the invention, a fine powdered insoluble calcium salt is specifically admixed with a milk blend prior to fermentation.

ISSUES

Whether or not claims 1-22 and 25-72 are patentable under 35 U.S.C. § 103 over Fleury et al. (U.S. Patent No. 5,820,903 which is also assigned to General Mills, Inc.) in view of Hansen et al. (U.S. Patent No. 5,449,523).

The applicant disagrees with the Examiner's positions for at least the following reasons:

- 1) The main reference to Fleury et al. specifically teaches away from the present invention, particularly with respect to the timing of adding calcium;
- 2) Fleury et al. and Hansen et al. teach away from each other, particularly with respect to mandated pH ranges such that modifying Fleury et al. in view of Hansen et al. would destroy specific desired features of the invention set forth in Fleury et al. wherein one of ordinary skill in the art would not consider the combination obvious;
- 3) The prior art references, even as combined by the Examiner, lack at least one limitation specified in the claims, specifically the utilization of a fine powered calcium phosphate of reduced particle having a mean diameter $\leq 6\mu\text{m}$, which the Examiner has improperly rejected without any teaching in the art; and
- 4) The applied prior art and the rejection of the claims set forth by the Examiner fail to address other claimed features, including the making of products not even contemplated by the applied prior art.

GROUPING OF CLAIMS

Independent claims 1, 30, 40 and 52 are seen to be independently patentable; dependent claims 5, 9, 22, 36, 44 and 53 are also seen to be independently patentable; and the remaining claims, at least for purposes of simplifying issues for this appeal, stand or fall upon a determination of the issue of obviousness of the more specific of a respective one of claims 1, 5, 9, 22, 30, 36, 44, 52 and 53 from which they depend.

In general, it is submitted that there are a few common themes concerning differences between the present invention and the applied prior art such that certain arguments for patentability are common throughout the claims. However, certain individual arguments for patentability also exist, as will be presented below.

ARGUMENTS

I. Brief Legal Analysis

The test for patentability under 35 U.S.C. §103 is basically whether the differences between the claimed subject matter, considered as the whole, and the prior art would have been obvious at the time the invention was made. Reaching this determination, the skill and content of the prior art, the differences between the prior art and the claimed subject matter and the level of ordinary skill in the art must be considered, along with the relevant secondary issues. *Graham v. John Deere Co.*, 381 U.S. 1, 148 USPQ 459 (1966).

A proper rejection under 35 U.S.C. §103 cannot be based on hindsight knowledge of the invention under consideration for the sole basis of attempting to meet the recitations of the claims. Specifically, the CAFC in *Environmental Designs, Ltd. v. Union Oil Co. of Cal.* 218 USPQ 865, 870 (1983) stated:

All the pieces of the present invention were known in the art, ... That all elements of an invention may have been old (the normal situation), or some old and some new, or all new, is however, simply irrelevant. Virtually all inventions are combinations and virtually all are combinations of old elements. A court must consider what the prior art as a whole would have suggested to one skilled in the art (Case citations).

Further, the CAFC in *In re Gordon*, 221, USPQ 1125, 1127 (1984) stated:

The mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification. (Case citations.)

Furthermore, the CAFC in *American Hoist & Derrick Co., v. Sowa & Sons, Inc.*, 220 USPQ 763, 771 (1984) quoted:

A patentable invention... may result even if the inventor has in effect, merely combined features, old in the art, for their known purpose, without producing anything beyond the results inherent in their use. (Emphasis theirs.)

Similarly, the Court of Appeals for the Federal Circuit *In re Sernaker*, 702 F.2d 989, 217 USPQ 1, 5 (1983) stated:

We may assume, for purposes of this decision, that all the prior art references in this case are sufficiently related to one another and to a related and common art, that the hypothetical person skilled in the art must be presumed to be familiar with all of them. That being so, the next questions are (a) whether a combination of the teachings of all or any of the references would have suggested (expressly or by implication) the possibility of achieving further improvement by combining such teachings long the line of the invention in suit, and (b) whether the claimed invention achieved more than a combination which any or all of the prior art references suggested, expressly or by reasonable implication.

References must be evaluated by ascertaining the facts fairly disclosed therein as a whole. It is impermissible to first ascertain factually what [applicant] did and then view

the prior art in such a manner as to select from the random facts of that art only those which may be modified and then utilized to reconstruct applicant's invention from such prior art. *In re Shuman and Meinhardt*, 150 USPQ 54 (CCPA 1966).

The mere fact that prior art may be modified to reflect features of a claimed invention does not make the modification, and hence the claimed invention, obvious unless desirability of such modification is suggested in the prior art. The claimed invention cannot be used as an instruction manual or "template" to piece together teachings of prior art so that the claimed invention is rendered obvious. *In re Fritch*, 23 USPQ 2nd 1780 (CAFC 1992).

If the modifications are suggested by the Examiner in order to achieve the claimed invention would destroy the fundamental characteristics of the base reference, the rejection is improper. *In re Rosin* 673 F.2d 388, 213 USPQ 247.

The burden is upon the Patent Office to supply the factual basis supporting the rejection. It must be shown why a person skilled in the art would find it obvious to depart from the teachings of a reference, when the issue is an obvious matter of choice. *Lipscombe's Walker on Patents*, Vol. 4, Section 12:14, page 45, citing *In re Warner*, 379 F.2d 1011, 154 USPQ 173 (1967), *In re Bezombes*, 420 F.2d 1070, 164 USPQ 387 (CCPA 1970).

Therefore, it is clear that it is the PTO that has to establish a prima facie case of obviousness and "obvious can not be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentives supporting the combination." *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984) and *Ray Geiger*, 815 F.2d 686 (Fed. Cir. 1987). It is also important to note that the mere fact that the prior art disclosures might suggest to one of ordinary skill in the art to try various combinations of

known elements does not establish a prima facie case of obviousness under 35 U.S.C.

§103. *Ray Geiger supra*.

II. Specific Arguments Related To Issues Set Forth Above

A. Main Reference Teaches Away from Present Invention

In the outstanding Office Action, the Examiner states that Fleury et al. essentially discloses the present invention except that the claims of the present application require the calcium to be added prior to inoculation, fermentation or pasteurization. To this end, the Examiner relies upon the secondary reference to Hansen et al. to set forth the process of preparing a fortified yogurt wherein calcium is added prior to inoculation. With respect to this combination, it is considered to have a few major shortcomings. First of all, it should be specifically noted that Fleury et al. teaches away from prefermentation addition of calcium. In column 4, lines 63 through column 5, line 2 of Fleury et al, it is specifically stated that calcium fortification methods of the patent "rely upon post fermentation rather than prefermentation addition." The patent goes on to discuss perceived problems with prefermentation and avoiding it. Therefore, it is respectfully submitted that Fleury et al. teaches away from the present invention such that one of ordinary skill in the art, regardless of the teachings in Hansen et al., would not look to modifying Fleury et al. to utilize prefermentation addition. This teaching away characteristic is indicia of non-obviousness under *Graham v. Deere* such as it is respectfully submitted that the combination presented is improper for each of the independent claims, and particularly dependent claim 5.

B. The Main References Teach Away From and Are Incompatible With Each Other

Another major distinction in these references which is seen to teach away from the combination presented is that Hansen et al. discloses that it is imperative that chelating

and/or alkaline agents be added in order to specifically keep the pH of the yogurt base mix above a required level of about 6.7 prior to pasteurization. On the other hand, Fleury et al. specifically teaches to maintain the base within a few tenths of the pH of the yogurt and, as more specifically set forth in column 6, lines 21-25, between about 4.0 and 4.6. Since Hansen et al. highly emphasizes that the chelating and/or alkaline agents must be added and that the pH must be maintained above about 6.7 in order for the invention disclosed therein to properly function, modifying Fleury et al. in view of Hansen et al. would greatly alter the mandated pH characteristics set forth by Fleury et al., thereby destroying the reference. In other words, the Hansen et al. arrangement requires the chelating and/or alkaline agents and the pH above about 6.7 to function as disclosed, while Fleury et al. calls for a low pH. Surely, one could not maintain the pH desired by Fleury et al. if modified by Hansen et al. which requires the high pH to function. It is considered improper to simply select the prefermentation feature of Hansen et al. for use in the combination without the disclosed requirements for enabling the invention. Instead, the teachings in Hansen et al. must be considered as a whole. For this reason, it is also submitted that one of ordinary skill in the art would not make the combination presented by the Examiner. It is considered that this argument is relevant to the combination applied against each of the independent claims, and particularly dependent claim 36.

C. Prior Art Does Not Address Important Claim Limitations

Clearly, throughout the specification and claims, the fact that the mean diameter of the calcium particles must be less than or equal to six microns is heavily emphasized. For instance, all of the originally filed independent claims include such a limitation. The specification brings this point out most particularly on page 10, lines 22-24 and in the Abstract. That is, in accordance with each of the independent claims in this application, the overall calcium particles utilized in accordance with the invention must meet this six micron or less diameter limitation. It is respectfully submitted that none of the prior art

specifically discloses this limitation and this limitation has not been given proper patentable weight. In fact, it was not until the Final Office Action that this limitation was even addressed. In general, it appears that the Examiner acknowledges that the prior does not disclose or suggest this limitation, but still holds that "It is not seen that Applicant has established criticality to the claimed diameter."

The secondary reference to Hansen et al. does not disclose any corresponding particle size limitation. On the other hand, Fleury et al., which is assigned to the same Assignee as the present invention and to which the present invention is considered to be an improvement over, discloses utilizing calcium phosphate with a particle size of less than 150 microns. This disclosure is clearly set forth in the abstract and each of the independent claims in the patent. However, in all fairness, the specification has some disclosure in column 6, particularly lines 36-48, which discusses smaller particle sizes that can be as small as four microns. In any event, at best, this patent teaches having around 90% less than seven microns. Simply stated, such a small particle size requirement was not important in the post fermentation arrangement disclosed in Fleury et al. as this patented arrangement employs particle sizes that can range up to 150 microns. On the other hand, particular steps are taken in accordance with the present invention to ensure that the entire mean range of calcium particles are maintained at or below six microns.

Contrary to that set forth by the Examiner, it is submitted that criticality has been shown by the Applicant concerning this feature of the invention. For instance, note the above-referenced portion on page 10 starting with "Most importantly,...", as well as the discussion continuing through to the top of page 11 in referring to the problems encountered with larger particle sizes. It is hard to imagine placing a greater emphasis on this aspect of the invention in the written materials than referring to it as "most important". The specification even discloses the exact sieves employed in connection with the most preferred embodiment of the invention to achieve the desired particle sizing

(see Page 11, lines 5-10). In any case, without a specific teaching to this effect, it is respectfully submitted that the claims are distinguished over this known prior art. This particle size feature of the invention is required in each of the independent claims, as well as more specifically in dependent claim 44.

D. Prior Art and Rejection Applied Fail to Address Other Claim Limitations

Another point set forth in the claims of the present application, which is not at all addressed in the Final Office Action, is that both Fleury et al. and Hansen et al. are specifically concerned with forming yogurt. However, the Examiner will note that certain claims in the present application are concerned with the formation of milk. Although the prior art does disclose the possibility of making other dairy products such as sour cream, pudding or cheese, none of the prior art is concerned with making a milk beverage having an enhanced calcium content by the addition of calcium particles with a mean diameter less or equal to six microns prior to pasteurization such as set forth in many of the claims. To this end, the Examiner's attention is drawn to, for example, method claims 22 and 40, as well as product claims 53-57, 63 and 65.

III. Summary Arguments/Final Comments

Unlike the present invention, the method of Fleury et al relies upon post fermentation rather than the prefermentation addition of the calcium (Column 4, line 63-column 5, line2). Fleury et al points out that post fermentation avoids problems associated with prefermentation addition, such as calcium precipitation. Therefore Fleury et al teaches away from the use of the prefermentation step of Hansen et al.

The Examiner states "Hansen et al is merely cited to disclose a process for preparing a fortified yogurt comprising the addition of calcium prior to inoculation." However, Hansen et al teaches that the fortification prior to inoculation requires the

addition of a chelating agent and a high pH. Both the present application and Fleury et al teach away from the use of a chelating agent (See Fleury et al at column 1 line 65-column 2, line 2; application at page 3, lines 20-24) and employ low pH's. Based on the teachings of Hansen et al, the prefermentation addition of calcium would fail without the use of a chelating agent and a high pH level. Therefore, the method of the present application achieves unexpected results. For instance, page 12 lines 24-28 of the application points out that "by the selection of such a finely powdered calcium phosphate", the added calcium does not "settle out during fermentation even when quiescently practiced."

Simply stated, none of the prior art discloses or suggests the particle size aspect of the invention which is actually the most important and advantageous feature disclosed and claimed in connection with the invention. This particle size requirement, particularly taken in conjunction with the prefermentation aspect of the invention, has been found to advantageously enable various high calcium content dairy products to be produced which rival much lower calcium content products in taste, texture and other characteristics needed to establish a commercially viable product.

The present specification discusses both the Hansen et al. patented arrangement, such as on Page 3, lines 7+, and the method of Fleury et al., such as on Page 13, lines 18-28, such that the Examiner has not presented anything new to the applicant who is likely well above one of ordinary skill in the art. However, regardless of these teachings, the present invention is considered to be a new and unobvious improvement in the art. The specification presented to the Examiner some drawbacks with the Hansen et al. arrangement and indicated that the Fleury et al. invention could be used in conjunction with the present invention. Regardless, these references, taken singly or in combination, did not and does not suggest to the Applicant the present invention.

None of the prior art even contemplates making a milk beverage with a total calcium content, achieved prior to pasteurization, of 125% to 500%.

IV. Conclusion

It is respectfully submitted that the Applicant has particularly pointed out various claim limitations not addressed in the Final Office Action or the prior art of record. Furthermore, there are various specific reasons why one of ordinary skill in the art would not combine the references in the manner suggested by the Examiner in an attempt to meet the present invention. Based on the above, it is submitted that the present invention, as claimed, is patentably defined over the known prior art such that the Examiner's rejection should be reversed.

Respectfully requested,



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Date: December 30, 2002

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APPENDIX OF CLAIMS

1. A method of producing a dairy product fortified with a fine powdered of calcium phosphate, comprising the steps of:
 - A. providing a warm pasteurized milk blend having a temperature of 40°C to 60°C comprising a milk blend having a native calcium content and sufficient amounts of calcium phosphate in powder form comprising particles having a mean diameter of $\leq 6\mu\text{m}$ to provide a total calcium content of 125% to 500% of the native calcium content.
2. The method of claim 1, additionally comprising the step of:
 - B. inoculating the warm pasteurized calcium phosphate fortified heat treated milk base with a starter culture to form an inoculated milk base.
3. The method of claim 2, additionally comprising the step of:
 - C. fermenting the inoculated milk base to provide a yogurt.
4. The method of claim 3, additionally comprising the step of:
 - D. cooling the yogurt to arrest the fermentation to provide a chilled yogurt having a viscosity of at least 1500 centipoise (at 5°C).
5. The method of claim 3, wherein the fermentation step is practiced quiescently.
6. The method of claim 4 additionally comprising the step of: adding the chilled yogurt to a container to form a filled yogurt container.
7. The method of claim 6 wherein the container is a cup.
8. The method of claim 6 wherein the container is a flexible tube fabricated from a flexible film.

9. The method of claim 4 additionally comprising the step of:
adding the inoculated milk base to a container prior to fermenting Step C.
10. The method of claim 6 wherein the chilled yogurt additionally comprises a fruit sauce.
11. The method of claim 1 wherein the milk blend comprises mammalian milk.
12. The method of claim 1 wherein the calcium source is selected from the group consisting of tricalcium phosphate, dicalcium phosphate, their hydrates, and mixtures thereof.
13. The method of claim 9 wherein additionally comprising about 5 to 15% by weight of the fermented dairy product of a fruit ingredient.
14. The method of claim 13 wherein the fermented dairy product is a yogurt having a viscosity of at least 2300 cps (at 5°C).
15. The method of claim 6 wherein the fermented dairy product is a yogurt and wherein the yogurt is free of a fruit ingredient.
16. The method of claim 6 wherein the calcium salt is tricalcium phosphate.
17. The method of claim 6 additionally comprising the step:
maintaining the chilled yogurt container at about 5°C to about 10 °C.
18. The method of claim 1 wherein the total calcium content ranges from about 0.25% to about 0.75%.

19. The method of claim of claim 1 wherein the milk blend comprises at least one mammalian milk ingredient.
20. The method of claim of claim 1 wherein the milk blend comprises at least one soybean milk ingredient.
21. The method of claim of claim 1 wherein the milk blend comprises is chocolate flavored.
22. The method of claim 1, additionally comprising the step of:
 - B. cooling the calcium fortified pasteurized milk blend to about 1°C to 10°C to form a calcium fortified refrigerated milk.
23. Canceled
24. Canceled
25. The product produced by the method of claim 1.
26. The product produced by the method of claim 3.
27. The product produced by the method of claim 4.
28. The product produced by the method of claim 7.
29. The product produced by the method of claim 22.

30. A fermented dairy product fortified with calcium comprising:
 - A. a quantity of fermented dairy product having a viscosity of at least 1500 cps (at 5°C), and
 - B. sufficient amounts of calcium phosphate, dispersed in the fermented dairy product to provide at least 251 mg of calcium per 170g (up to 1500 mg calcium per 170g) wherein the particle size of the calcium phosphate comprises particles having a mean diameter of $\leq 6\mu\text{m}$.
31. The fermented dairy product of claim 30 wherein the calcium phosphate is calcium phosphate tribasic.
32. The fermented dairy product of claim 30 wherein the fermented dairy product is yogurt.
33. The fermented dairy product of claim 30 wherein the dairy product is free of a fruit ingredient.
34. The fermented dairy product of claim 30 wherein the total calcium content is about 0.29 to 0.76% by weight.
35. The fermented dairy product of claim 31 wherein the calcium phosphate is evenly dispersed throughout the product.
36. The fermented dairy product of claim 30 wherein the pH of the product is about 4.4 to 4.6.
37. The fermented dairy product of claim 30 additionally comprising a high potency sweetener.

38. The fermented dairy product of claim 32 wherein the yogurt is a stirred style yogurt product.
39. The fermented dairy product of claim 32 wherein the yogurt is a cut set style yogurt product.
40. In a method of producing a fermented dairy product by inoculating a pasteurized milk blend having a native calcium content and fermenting, the improvement comprising:
adding calcium phosphate in particulate in powder form comprising particles having a mean diameter of $\leq 6\mu\text{m}$ to provide a total calcium content of 125% to 500% of the native calcium content of the milk blend prior to pasteurization.
41. The method of claim 40 wherein the fermented dairy product is yogurt.
42. The method of claim 41 wherein yogurt includes a live culture and has a viscosity of at least 2300 cps (at 5°C).
43. The method of claim 42 wherein the yogurt is free of a fruit ingredient.
44. The method of claim 42 wherein the calcium phosphate is tricalcium phosphate having a mean particle size of $\leq 5\mu\text{m}$.
45. The method of claim 44 wherein the yogurt is a stirred style yogurt.
46. The method of claim 44 wherein the yogurt is a cup set style yogurt.

47. The method of claim 46 wherein the added calcium comprises tribasic calcium phosphate.
48. The product prepared by the method of claim 40.
49. The product prepared by the method of claim 44.
50. The product prepared by the method of claim 49.
51. The method of claim 42 additionally comprising the step of forming the yogurt into an aerated soft-frozen yogurt product having a density of 0.5 to 0.8g/cc and a temperature of -5 to -8°C.
52. A calcium fortified milk based food product exhibiting improved nutrition and good organoleptic properties, comprising:
a pasteurized milk base comprising at least one milk ingredient and having a native calcium content, and sufficient amounts of sufficient amounts of calcium phosphate in powder form comprising particles having a mean diameter of $\leq 6\mu\text{m}$ to provide a total calcium content of 125% to 500% of the native calcium content.
53. The food product of claim 52 wherein the food product is a fluid milk.
54. The food product of claim 53 wherein the fluid milk is refrigerated milk.
55. The food product of claim 54 wherein the pasteurized milk base comprises at least a mammalian milk ingredient.
56. The food product of claim 54 wherein the fluid milk is chocolate flavored.

- 57. The food product of claim 53 wherein the fluid milk is UHT milk.
- 58. The food product of claim 52 wherein the food product is a cultured dairy product.
- 59. The food product of claim 58 wherein the cultured dairy product is a yogurt.
- 60. The food product of claim 59 wherein the cultured dairy product is a cheese.
- 61. The food product of claim 58 wherein the total calcium content ranges from about 0.25% to about 0.75%.
- 62. The food product of claim 52 additionally comprising a gelatinized starch.
- 63. The food product of claim 62 wherein the milk is chocolate flavored.
- 64. The food product of claim 63 wherein the food product additionally comprises a sweetener and is in the form of a pudding.
- 65. The food product of claim 52 wherein the milk ingredient includes a soybean milk.
- 66. The food product of claim 59 free of calcium carbonate.
- 67. The food product of claim 59 wherein the yogurt is a cup set style yogurt.
- 68. The food product of claim 67 additionally comprising about 1% to 15% of a fruit sauce.
- 69. The food product of claim 59 disposed within a sealed container fabricated from a flexible film.

- 70. The food product of claim 59 disposed within a sealed container fabricated from a flexible film in the form of a tube.
- 71. The fermented dairy product of claim 30 aerated to a density of 0.5 to 0.9 g/cc.
- 72. The fermented dairy product of claim 71 frozen to -15 to -2°C.